

REMARKS

Claims 1 and 17 have been amended, claims 13-16 and 20 have been canceled, and new claims 21-25 have been added. Claims 1-12, 17-19 and 21-25 are now pending for the Examiner's consideration.

New claims 21-25 have been added to recite particular embodiments of the invention, and are supported, for example, by the claims as filed. No new matter is added.

Applicants respectfully request reconsideration and allowance of the pending claims, in light of the foregoing amendments and following remarks.

In response to the Examiner's suggestion on page 2 of the Office Action, Applicants note that application serial nos. 10/367,008 and 10/658,801 are still pending. Thus, the specification reflects the current status of those applications.

Claims 1, 13, 17 and 20 were rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth on pages 2-4 of the Office Action. Claims 13 and 20 have been canceled. Without acquiescing to the merits of the rejection, in order to expedite prosecution, claims 1 and 17 have been amended to recite the specific cancers for which example data is shown in the specification. Thus, Applicants believe the rejection has been overcome and respectfully request that it be withdrawn.

Claims 14-16 were rejected under 35 U.S.C. § 112, second paragraph, for the reasons set forth on pages 4-5 of the Office Action. Claims 14-16 have now been canceled, and the rejection is moot.

Claims 1-20 were rejected under 35 U.S.C. § 103(a) as unpatentable over the references cited on page 6 of the Office Action. Applicants respectfully traverse.

The Examiner argues that the claimed combinations would have been obvious since one skilled in the art would assume the combinations would give additive effects in the absence of evidence to the contrary. However, Applicants have shown that the claimed combinations are effective in treating several cancer types and further, show synergistic rather than merely additive effects. For example, in Example 1 on page 60, first two paragraphs, docetaxel alone at a dose of 5 mg/kg showed no efficacy in the MX-1 human breast carcinoma subcutaneous tumor model, but a combination of Compound 1 and 5 mg/kg of docetaxel showed "markedly enhanced inhibition of tumor growth relative to the non-effective 5 mg/kg Docetaxel and relative to 40 mg/kg/day of Compound 1 (Day 27: 55% inhibition, $p = 0.04$).". Similarly, in Example 2, page 61, last paragraph, docetaxel alone at 5 mg/kg showed no efficacy whereas, "The combination of daily dosing of Compound 1 with 5 mg/kg Docetaxel once a week for three weeks resulted in markedly enhanced inhibition of tumor growth relative to the non-effective 5 mg/kg Docetaxel and relative to 40 mg/kg/day of Compound 1 (Day 28: 43% inhibition, $p = 0.08$ - trending toward significance)" (page 61, first paragraph). These examples clearly show that combinations of the

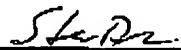
invention show a synergistic effect that is not taught or suggested in the combination of cited references. Accordingly, Applicants request that the rejection under § 103(a) be reconsidered and withdrawn.

Should there be any issues that have not been addressed to the Examiner's satisfaction, Applicants invite the Examiner to contact the undersigned attorney.

If any fees other than those submitted herewith are due in connection with this response, including the fee for any required extension of time (for which Applicant hereby petitions), please charge such fees to Deposit Account No. 500329.

Respectfully submitted,

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